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Gresham

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(54) **TOOL MEMBER COVER AND COVER
DEPLOYMENT DEVICE**

A61B 17/1155 (2013.01); *A61B 17/3494*
(2013.01); *A61B 2017/00287* (2013.01); *A61B*
2017/3435 (2013.01); *A61B 2019/0267*
(2013.01); *A61B 2019/4027* (2013.01)

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A61B 2017/3435
USPC 604/263; 606/114, 127, 205–211, 219;
227/175.1–182.1

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,388,847	A	6/1968	Kasulin et al.
3,552,626	A	1/1971	Astafiev
3,638,652	A	2/1972	Kelley
3,894,706	A	7/1975	Mizusawa
4,198,982	A	4/1980	Fortner et al.
4,207,898	A	6/1980	Becht
4,227,537	A	10/1980	Suciu et al.

(Continued)

FOREIGN PATENT DOCUMENTS

CA	908529	8/1972
DE	1057729	5/1959

(Continued)

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<i>A61B 17/068</i>	(2006.01)
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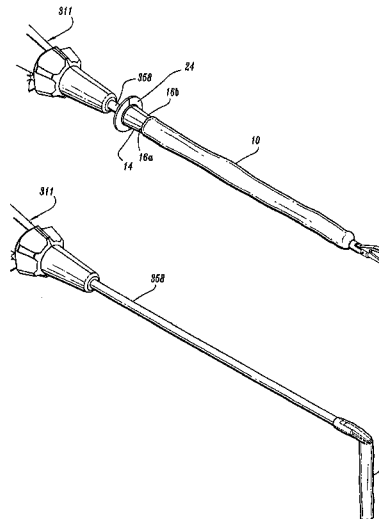
(52) **U.S. Cl.**

CPC *A61B 17/00234* (2013.01); *A61B 17/068*
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(57) **ABSTRACT**

A surgical instrument including a tool member cover and a
cover deployment device are disclosed. The cover is sup-
ported adjacent to or on the tool assembly of the surgical
instrument and is movable from a first position in which the
tool assembly is uncovered to a second position in which the
tool assembly is at least partially encompassed by the cover.
The deployment device is provided for moving the cover from
the first position to the second position.

19 Claims, 11 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

4,289,133	A	9/1981	Rothfuss	5,395,030	A	3/1995	Kuramoto et al.
4,304,236	A	12/1981	Conta et al.	5,403,333	A	4/1995	Kaster et al.
4,319,576	A	3/1982	Rothfuss	5,404,870	A	4/1995	Brinkerhoff et al.
4,350,160	A	9/1982	Kolesov et al.	5,411,508	A	5/1995	Bessler et al.
4,351,466	A	9/1982	Noiles	5,433,721	A	7/1995	Hooven et al.
4,379,457	A	4/1983	Gravener et al.	5,437,684	A	8/1995	Calabrese et al.
4,473,077	A	9/1984	Noiles et al.	5,439,156	A	8/1995	Grant et al.
4,476,863	A	10/1984	Kanshin et al.	5,441,507	A	8/1995	Wilk et al.
4,485,817	A	12/1984	Swiggett	5,443,198	A	8/1995	Viola et al.
4,488,523	A	12/1984	Shichman	5,445,644	A	8/1995	Pietrafitta et al.
4,505,272	A	3/1985	Utyamyshev et al.	5,447,514	A	9/1995	Gerry et al.
4,505,414	A	3/1985	Filipi	5,454,825	A	10/1995	Van Leeuwen et al.
4,550,870	A	11/1985	Krumme et al.	5,470,006	A	11/1995	Rodak
4,573,468	A	3/1986	Conta et al.	5,474,223	A	12/1995	Viola et al.
4,576,167	A	3/1986	Noiles	5,497,934	A	3/1996	Brady et al.
4,592,354	A	6/1986	Rothfuss	5,522,534	A	6/1996	Viola et al.
4,603,693	A	8/1986	Conta et al.	5,533,661	A	7/1996	Main et al.
4,606,343	A	8/1986	Conta et al.	5,588,579	A	12/1996	Schnut et al.
4,646,745	A	3/1987	Noiles	5,609,285	A	3/1997	Grant et al.
4,657,020	A	4/1987	Lifton	5,632,433	A	5/1997	Grant et al.
4,667,673	A	5/1987	Li	5,639,008	A	6/1997	Gallagher et al.
4,671,445	A	6/1987	Barker et al.	5,658,300	A	8/1997	Bito et al.
4,700,703	A	10/1987	Resnick et al.	5,665,073	A	9/1997	Bulow et al.
4,703,887	A	11/1987	Clanton et al.	5,669,918	A	9/1997	Balazs et al.
4,708,141	A	11/1987	Inoue et al.	5,685,474	A	11/1997	Seeber
4,754,909	A	7/1988	Barker et al.	5,709,335	A	1/1998	Heck
4,817,847	A	4/1989	Redtenbacher et al.	5,715,987	A	2/1998	Kelley et al.
4,873,977	A	10/1989	Avant et al.	5,718,360	A	2/1998	Green et al.
4,877,033	A	10/1989	Seitz, Jr.	5,720,755	A	2/1998	Dakov
4,893,662	A	1/1990	Green et al.	5,732,872	A	3/1998	Bolduc et al.
4,903,697	A	2/1990	Resnick et al.	5,758,814	A	6/1998	Gallagher et al.
4,907,591	A	3/1990	Vasconcellos et al.	5,762,604	A	6/1998	Kieturakis
4,917,114	A	4/1990	Green et al.	5,799,857	A	9/1998	Robertson et al.
4,957,499	A	9/1990	Lipatov et al.	5,836,503	A	11/1998	Ehrenfels et al.
5,005,749	A	4/1991	Aranyi	5,839,639	A	11/1998	Sauer et al.
5,042,707	A	8/1991	Taheri	5,855,312	A	1/1999	Toledano
5,047,039	A	9/1991	Avant et al.	5,860,581	A	1/1999	Robertson et al.
5,061,246	A	10/1991	Anapliotis	5,868,760	A	2/1999	McGuckin, Jr.
5,104,025	A	4/1992	Main et al.	5,881,943	A	3/1999	Heck et al.
5,119,983	A	6/1992	Green et al.	5,915,616	A	6/1999	Viola et al.
5,122,156	A	6/1992	Granger et al.	5,947,363	A	9/1999	Bolduc et al.
5,139,513	A	8/1992	Segato	5,951,576	A	9/1999	Wakabayashi
5,158,222	A	10/1992	Green et al.	5,957,363	A	9/1999	Heck
5,188,638	A	2/1993	Tzakis	5,993,468	A	11/1999	Rygaard
5,193,731	A	3/1993	Aranyi	6,024,741	A	2/2000	Williamson et al.
5,197,648	A	3/1993	Gingold	6,050,472	A	4/2000	Shibata
5,197,649	A	3/1993	Bessler et al.	6,053,390	A	4/2000	Green et al.
5,205,459	A	4/1993	Brinkerhoff et al.	6,068,636	A	5/2000	Chen
5,221,036	A	6/1993	Takase	6,083,241	A	7/2000	Longo et al.
5,222,963	A	6/1993	Brinkerhoff et al.	6,102,271	A	8/2000	Longo et al.
5,253,793	A	10/1993	Green et al.	6,117,148	A	9/2000	Ravo et al.
5,261,920	A	11/1993	Main et al.	6,119,913	A	9/2000	Adams et al.
5,271,543	A	12/1993	Grant et al.	6,126,058	A	10/2000	Adams et al.
5,271,544	A	12/1993	Fox et al.	6,149,667	A	11/2000	Hovland et al.
5,275,322	A	1/1994	Brinkerhoff et al.	6,176,413	B1	1/2001	Heck et al.
5,285,810	A	2/1994	Allen et al.	6,179,195	B1	1/2001	Adams et al.
5,285,944	A	2/1994	Green et al.	6,193,129	B1	2/2001	Bittner et al.
5,285,945	A	2/1994	Brinkerhoff et al.	6,203,553	B1	3/2001	Robertson et al.
5,292,053	A	3/1994	Bilotti et al.	6,209,773	B1	4/2001	Bolduc et al.
5,309,927	A	5/1994	Welch	6,241,140	B1	6/2001	Adams et al.
5,312,024	A	5/1994	Grant et al.	6,253,984	B1	7/2001	Heck et al.
5,314,435	A	5/1994	Green et al.	6,258,107	B1 *	7/2001	Balazs et al. 606/153
5,314,436	A	5/1994	Wilk	6,264,086	B1	7/2001	McGuckin, Jr.
5,318,221	A	6/1994	Green et al.	6,269,997	B1	8/2001	Balázs et al.
5,330,486	A	7/1994	Wilk	6,279,809	B1	8/2001	Nicolo
5,333,773	A	8/1994	Main et al.	6,302,311	B1	10/2001	Adams et al.
5,344,059	A	9/1994	Green et al.	6,315,770	B1 *	11/2001	de la Torre et al. 606/1
5,346,115	A	9/1994	Perouse et al.	6,318,765	B1	11/2001	Slais et al.
5,348,259	A	9/1994	Blanco et al.	6,338,737	B1	1/2002	Toledano
5,350,104	A	9/1994	Main et al.	6,343,731	B1	2/2002	Adams et al.
5,355,897	A	10/1994	Pietrafitta et al.	6,371,968	B1 *	4/2002	Kogasaka et al. 606/190
5,360,154	A	11/1994	Green	6,383,195	B1	5/2002	Richard
5,368,215	A	11/1994	Green et al.	6,387,105	B1	5/2002	Gifford, III et al.
5,370,647	A	12/1994	Graber et al.	6,398,795	B1	6/2002	McAlister et al.
5,392,979	A	2/1995	Green et al.	6,402,008	B1	6/2002	Lucas
				6,428,556	B1 *	8/2002	Chin 606/198
				6,450,390	B2	9/2002	Heck et al.
				6,478,210	B2	11/2002	Adams et al.
				6,488,197	B1	12/2002	Whitman

(56)

References Cited

U.S. PATENT DOCUMENTS

6,491,201	B1	12/2002	Whitman	
6,494,877	B2	12/2002	Odell et al.	
6,503,259	B2	1/2003	Huxel et al.	
6,517,566	B1	2/2003	Hovland et al.	
6,520,398	B2	2/2003	Nicolo	
6,533,157	B1	3/2003	Whitman	
6,578,751	B2	6/2003	Hartwick	
6,585,144	B2	7/2003	Adams et al.	
6,588,643	B2	7/2003	Bolduc et al.	
6,592,596	B1	7/2003	Geitz	
6,601,749	B2	8/2003	Sullivan et al.	
6,605,078	B2	8/2003	Adams	
6,623,227	B2	9/2003	Scott et al.	
6,626,921	B2	9/2003	Blatter et al.	
6,629,630	B2	10/2003	Adams	
6,631,837	B1	10/2003	Heck	
6,632,227	B2	10/2003	Adams	
6,632,237	B2	10/2003	Ben-David et al.	
6,659,327	B2	12/2003	Heck et al.	
6,676,671	B2	1/2004	Robertson et al.	
6,681,979	B2	1/2004	Whitman	
6,685,079	B2	2/2004	Sharma et al.	
6,695,198	B2	2/2004	Adams et al.	
6,695,199	B2	2/2004	Whitman	
6,716,222	B2	4/2004	McAlister et al.	
6,716,233	B1	4/2004	Whitman	
6,742,692	B2	6/2004	Hartwick	
6,752,822	B2	6/2004	Jespersen	
6,763,993	B2	7/2004	Bolduc et al.	
6,769,590	B2	8/2004	Vresh et al.	
6,769,594	B2	8/2004	Orban, III	
6,820,791	B2	11/2004	Adams	
6,827,246	B2	12/2004	Sullivan et al.	
6,840,423	B2	1/2005	Adams et al.	
6,866,178	B2	3/2005	Adams et al.	
6,872,214	B2	3/2005	Sonnenschein et al.	
6,874,669	B2	4/2005	Adams et al.	
6,884,250	B2	4/2005	Monassevitch et al.	
6,905,504	B1	6/2005	Vargas	
6,938,814	B2	9/2005	Sharma et al.	
6,971,988	B2	12/2005	Orban	
7,398,781	B1 *	7/2008	Chin	128/898
7,901,416	B2	3/2011	Nolan et al.	
2001/0000903	A1	5/2001	Heck et al.	
2001/0010320	A1	8/2001	Bolduc et al.	
2001/0054636	A1	12/2001	Nicolo	
2002/0016583	A1 *	2/2002	Cragg	604/500
2002/0020732	A1	2/2002	Adams et al.	
2002/0047036	A1	4/2002	Sullivan et al.	
2002/0063143	A1	5/2002	Adams et al.	
2002/0099393	A1 *	7/2002	Fleischman et al.	606/153
2002/0185516	A1	12/2002	Heck et al.	
2002/0185517	A1	12/2002	Vresh et al.	
2003/0019905	A1	1/2003	Adams et al.	

2003/0047582	A1	3/2003	Sonnenschein et al.
2003/0057251	A1	3/2003	Hartwick
2003/0065342	A1	4/2003	Nobis et al.
2003/0073981	A1	4/2003	Whitman et al.
2003/0089757	A1	5/2003	Whitman
2003/0111507	A1	6/2003	Nunez
2003/0127491	A1	7/2003	Adams et al.
2003/0132267	A1	7/2003	Adams et al.
2003/0139767	A1	7/2003	Jespersen
2003/0144675	A1	7/2003	Nicolo
2003/0178465	A1	9/2003	Bilotti et al.
2003/0183671	A1	10/2003	Mooradian et al.
2003/0192936	A1	10/2003	Hartwick
2003/0192937	A1	10/2003	Sullivan et al.
2003/0201301	A1	10/2003	Bolduc et al.
2003/0218047	A1	11/2003	Sharma et al.
2003/0222117	A1	12/2003	Orban, III
2004/0092960	A1	5/2004	Abrams et al.
2004/0092974	A1	5/2004	Gannoe et al.
2004/0118896	A1	6/2004	Sharma et al.
2004/0134964	A1	7/2004	Adams et al.
2004/0153124	A1	8/2004	Whitman
2004/0232198	A1	11/2004	Adams et al.
2005/0051597	A1	3/2005	Toledano
2005/0067454	A1	3/2005	Vresh et al.
2005/0087580	A1	4/2005	Orban, III
2005/0107813	A1	5/2005	Garcia
2005/0116009	A1	6/2005	Milliman
2005/0125009	A1	6/2005	Perry et al.
2005/0143758	A1	6/2005	Abbott et al.
2005/0145674	A1	7/2005	Sonnenschein et al.
2005/0145675	A1	7/2005	Hartwick et al.
2008/0306333	A1	12/2008	Chin

FOREIGN PATENT DOCUMENTS

DE	3301713	11/1989
EP	0152382	8/1985
EP	0173451	3/1986
EP	0190022	8/1986
EP	282157	9/1988
EP	0503689	9/1992
EP	0505138	9/1992
FR	1461464	12/1966
FR	1588250	4/1970
FR	1136020	12/1979
FR	2443239	12/1979
GB	1185292	3/1970
GB	2016991	9/1979
GB	2070499	9/1981
NL	7711347	10/1977
WO	8706448	11/1987
WO	8900406	1/1989
WO	9006085	6/1990
WO	WO02/056754	7/2002
WO	WO02/087447	11/2002

* cited by examiner

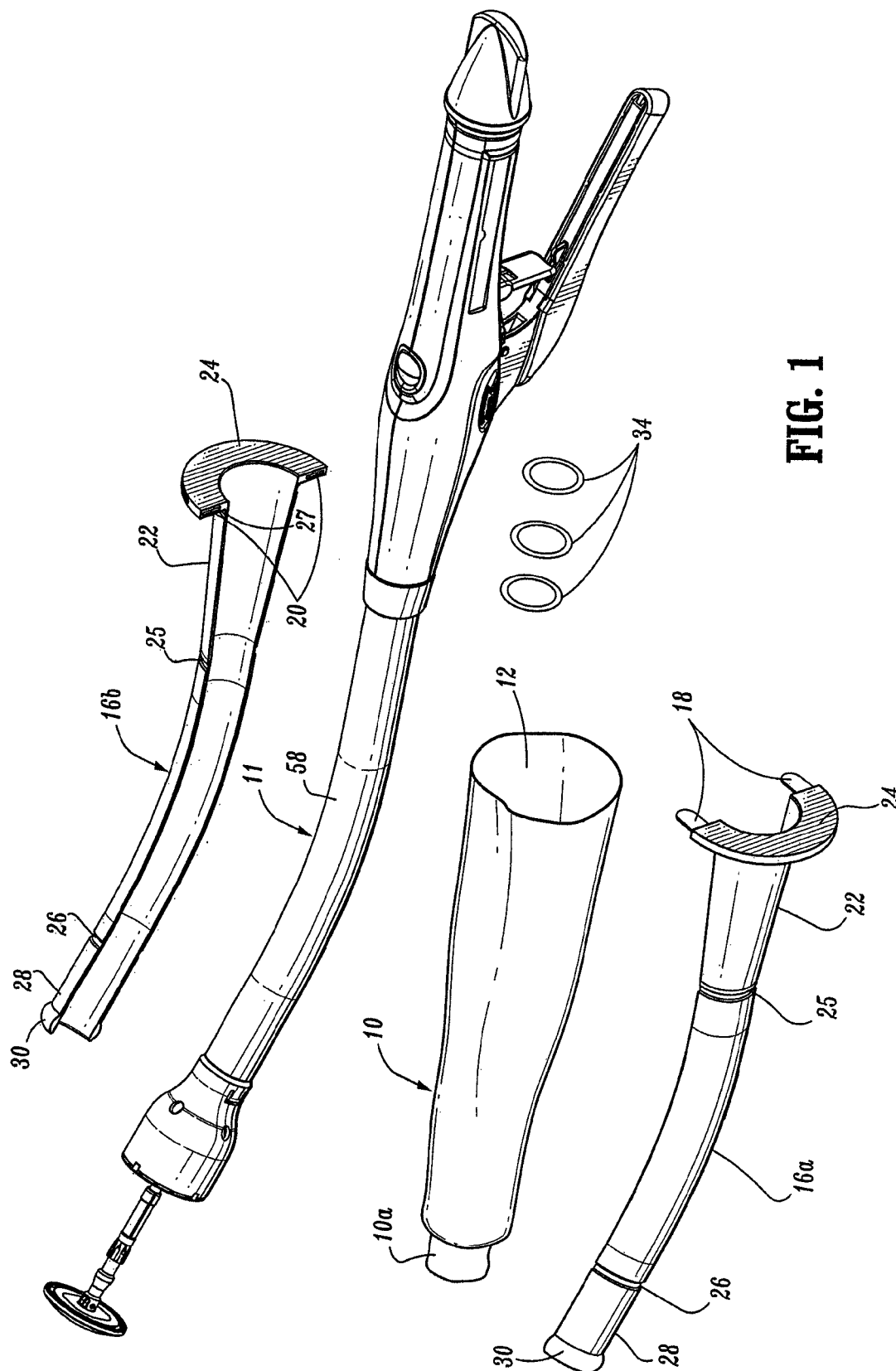


FIG. 1

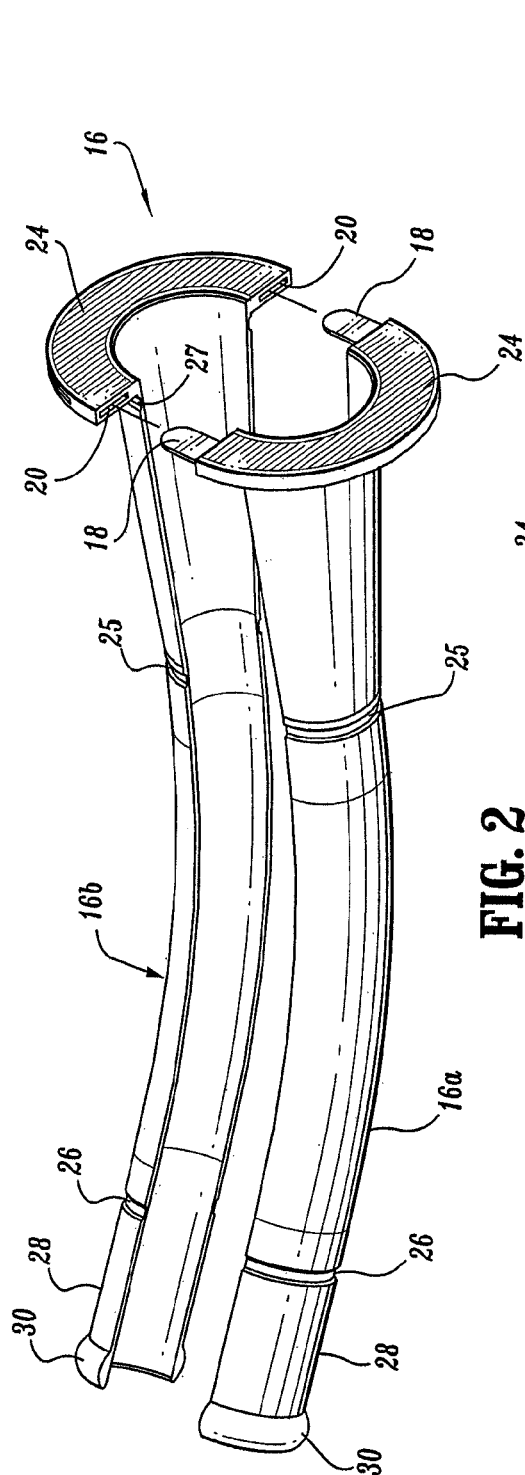


FIG. 2

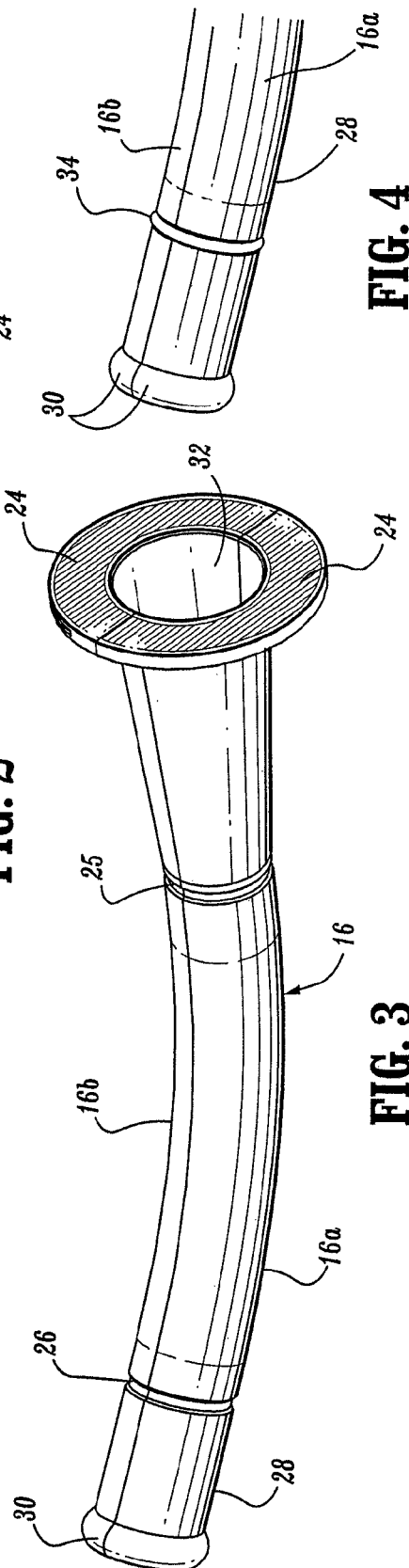


FIG. 4

FIG. 3

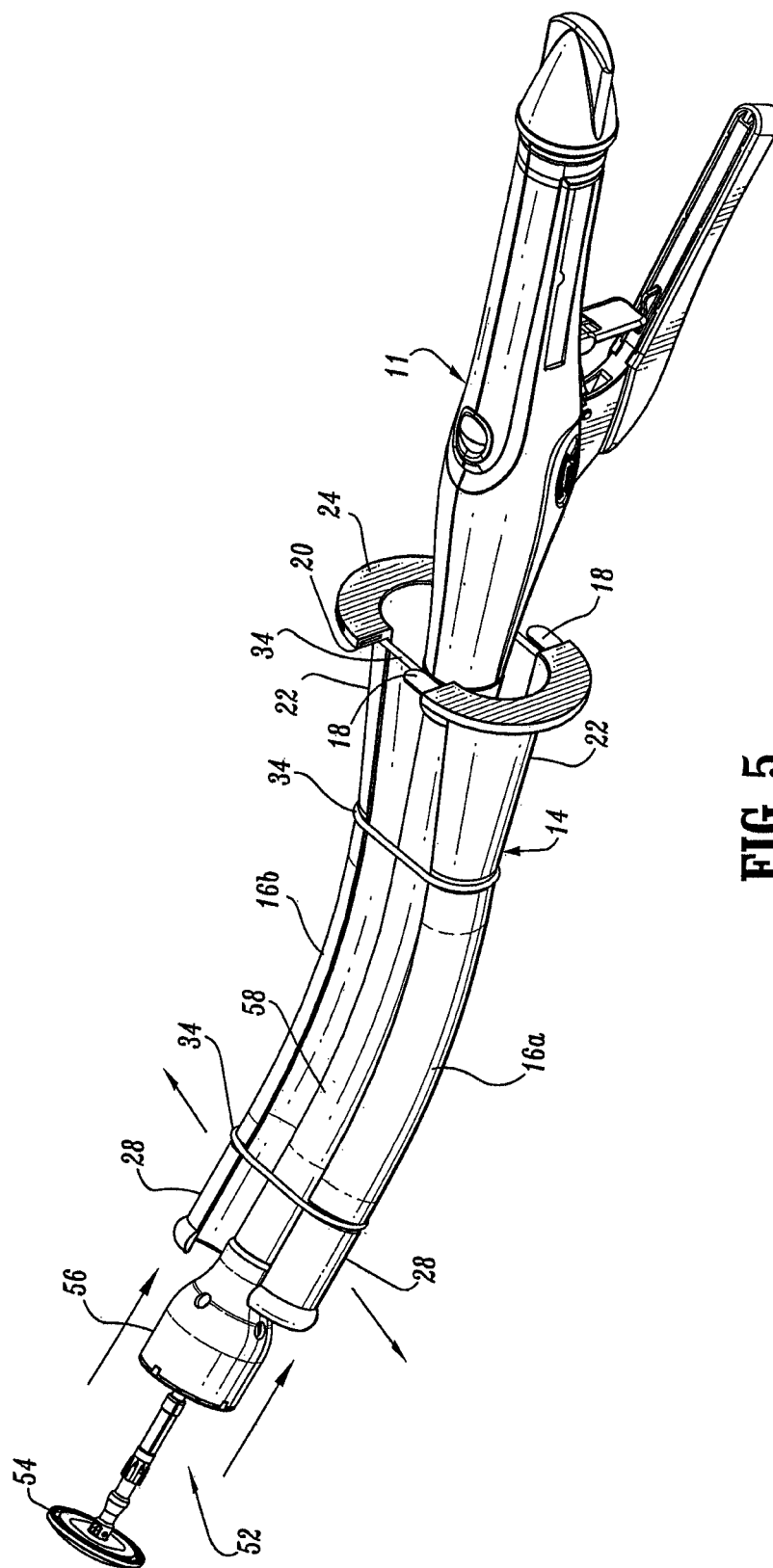
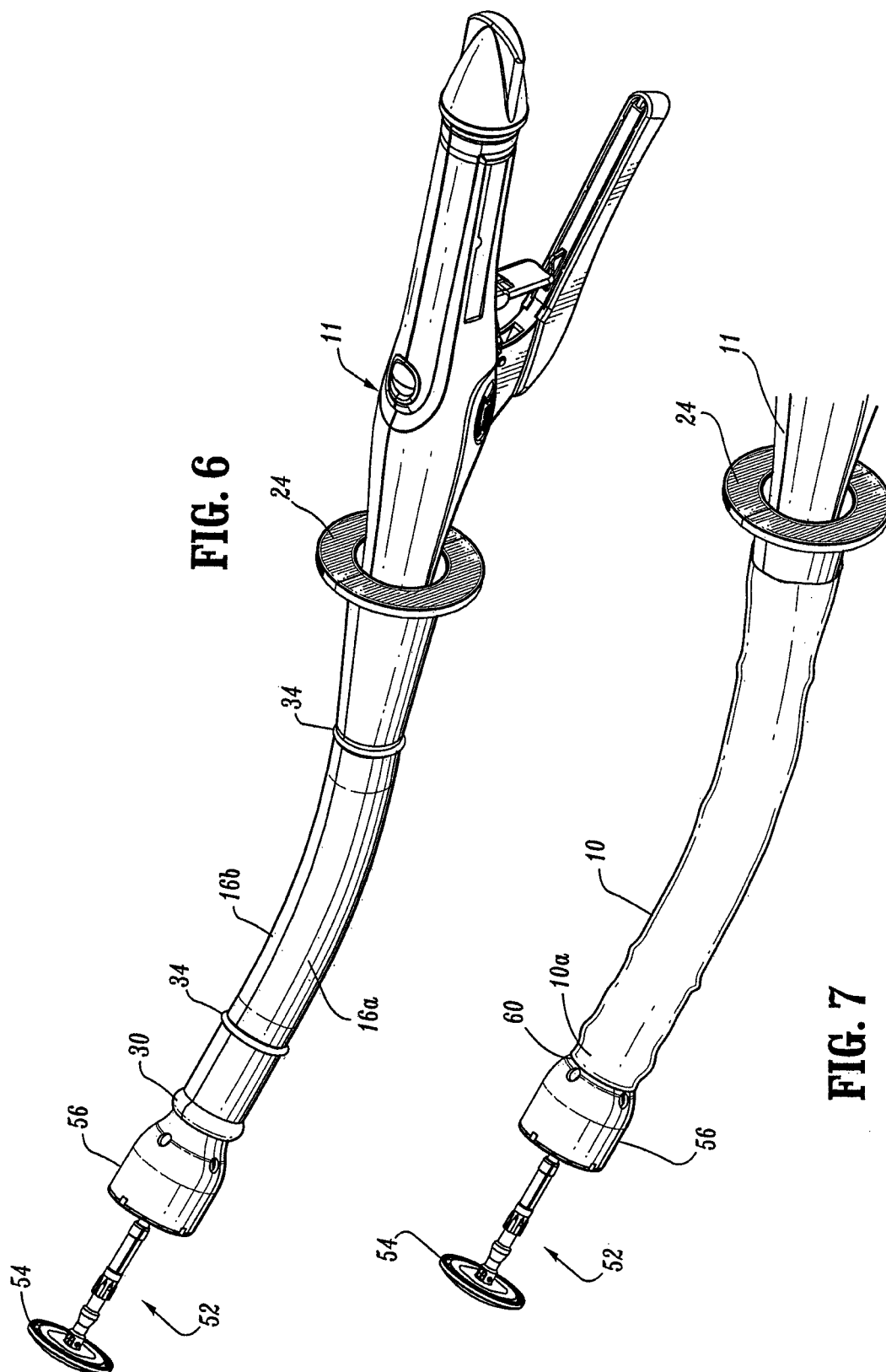
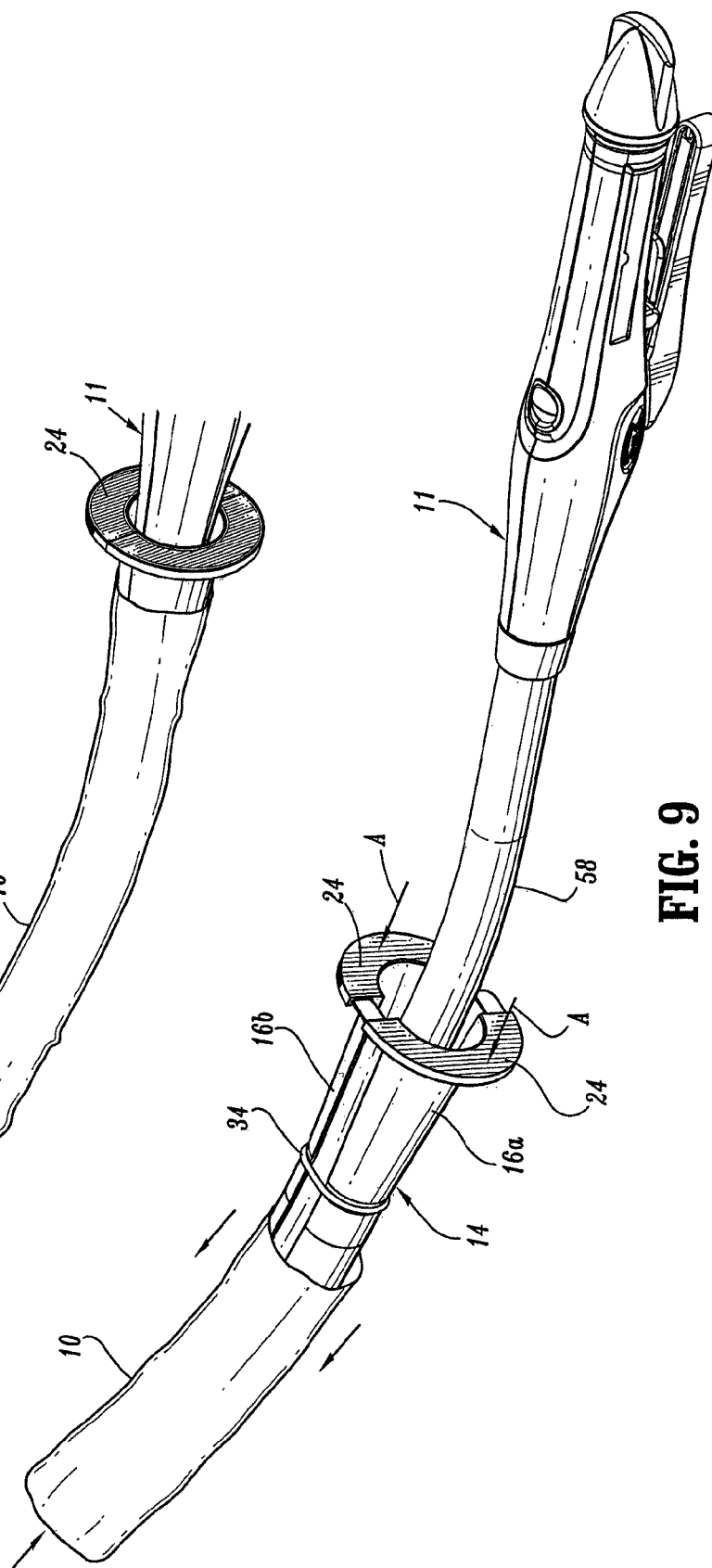
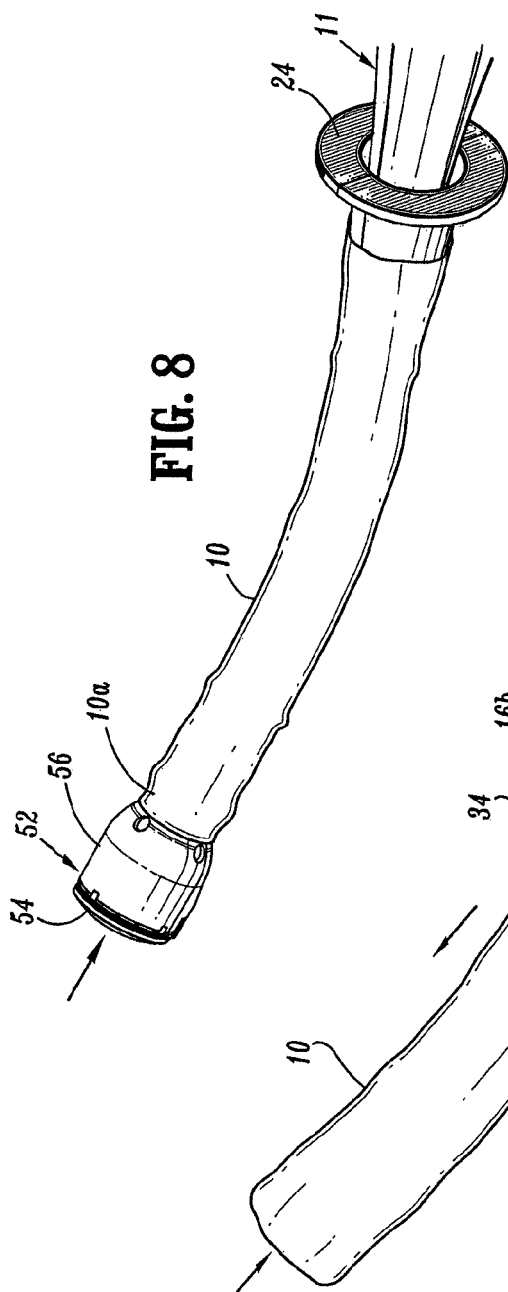


FIG. 5





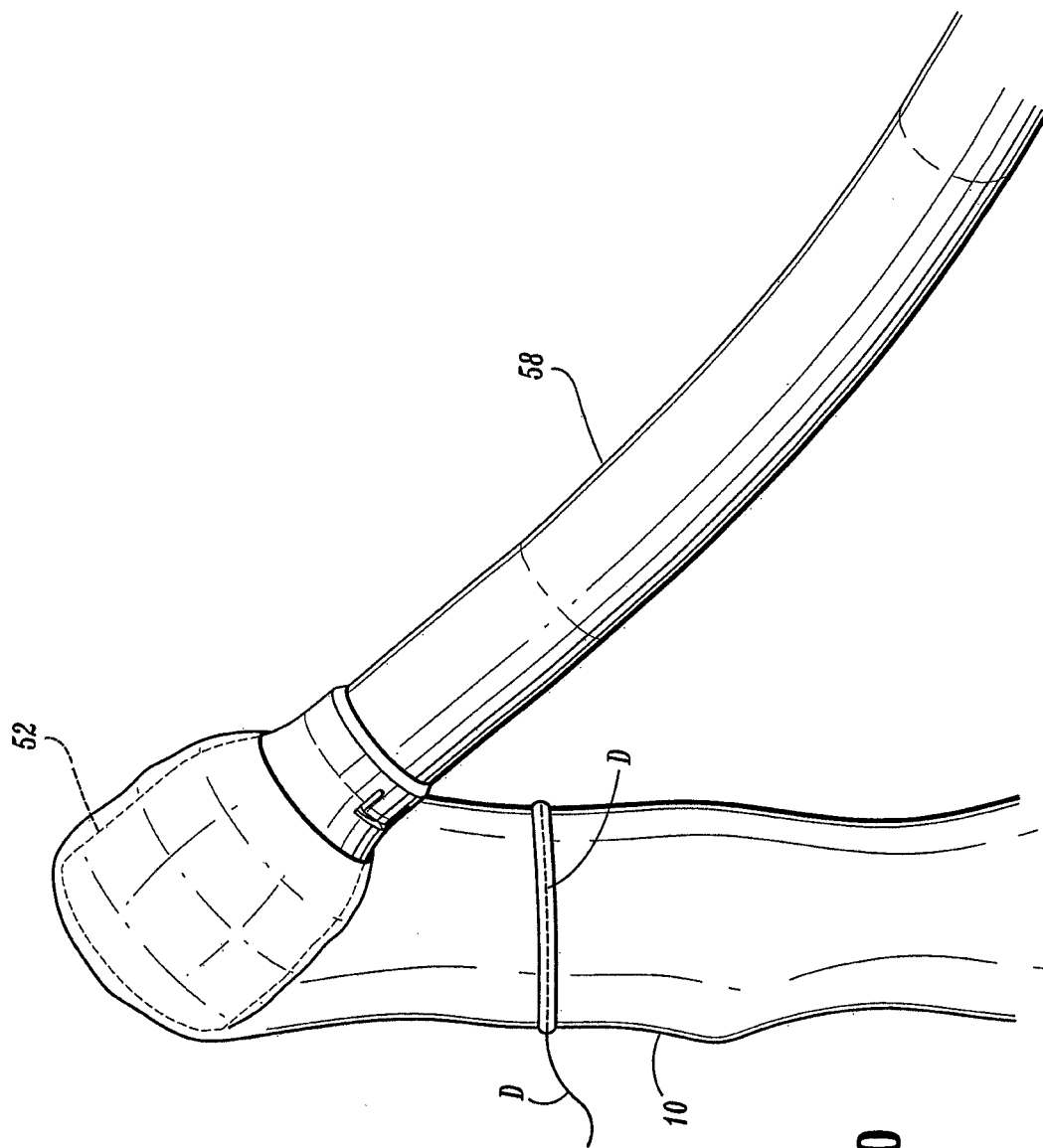


FIG. 10

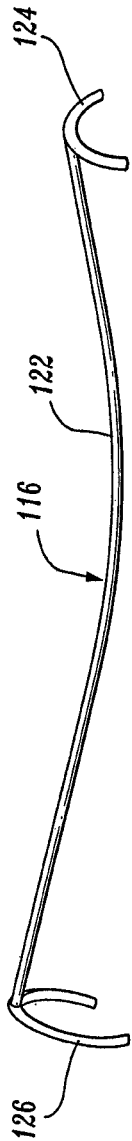


FIG. 11

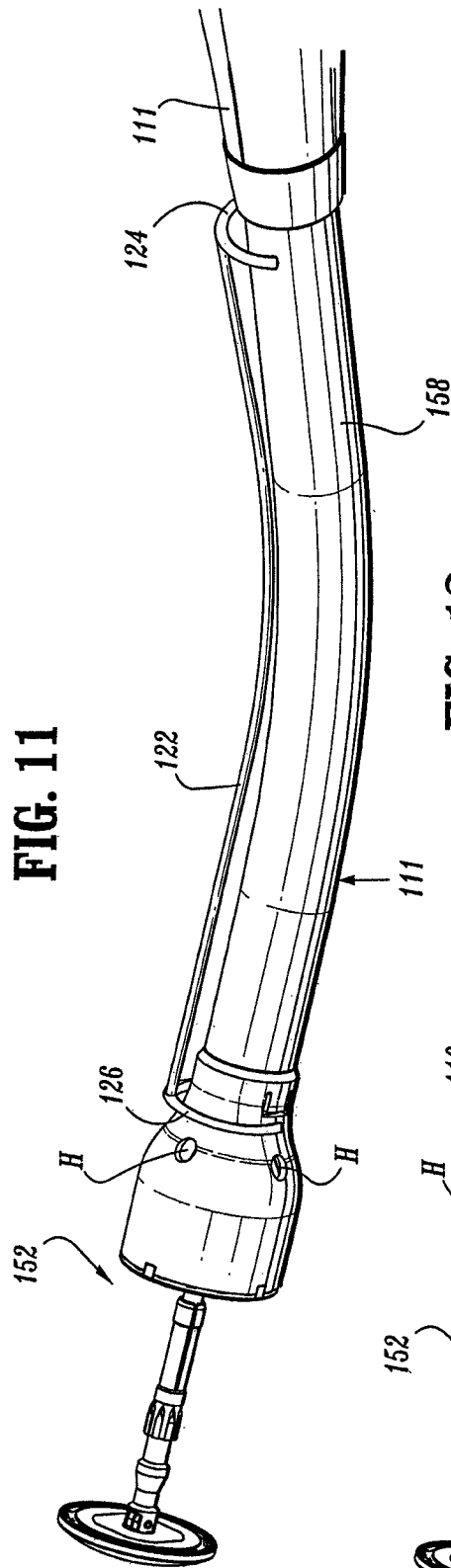


FIG. 12

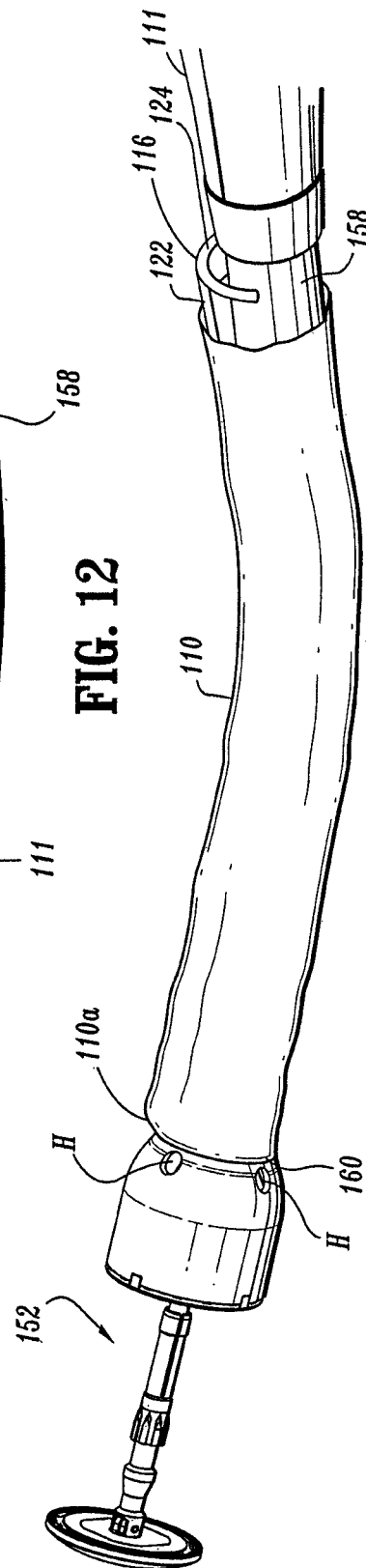


FIG. 13

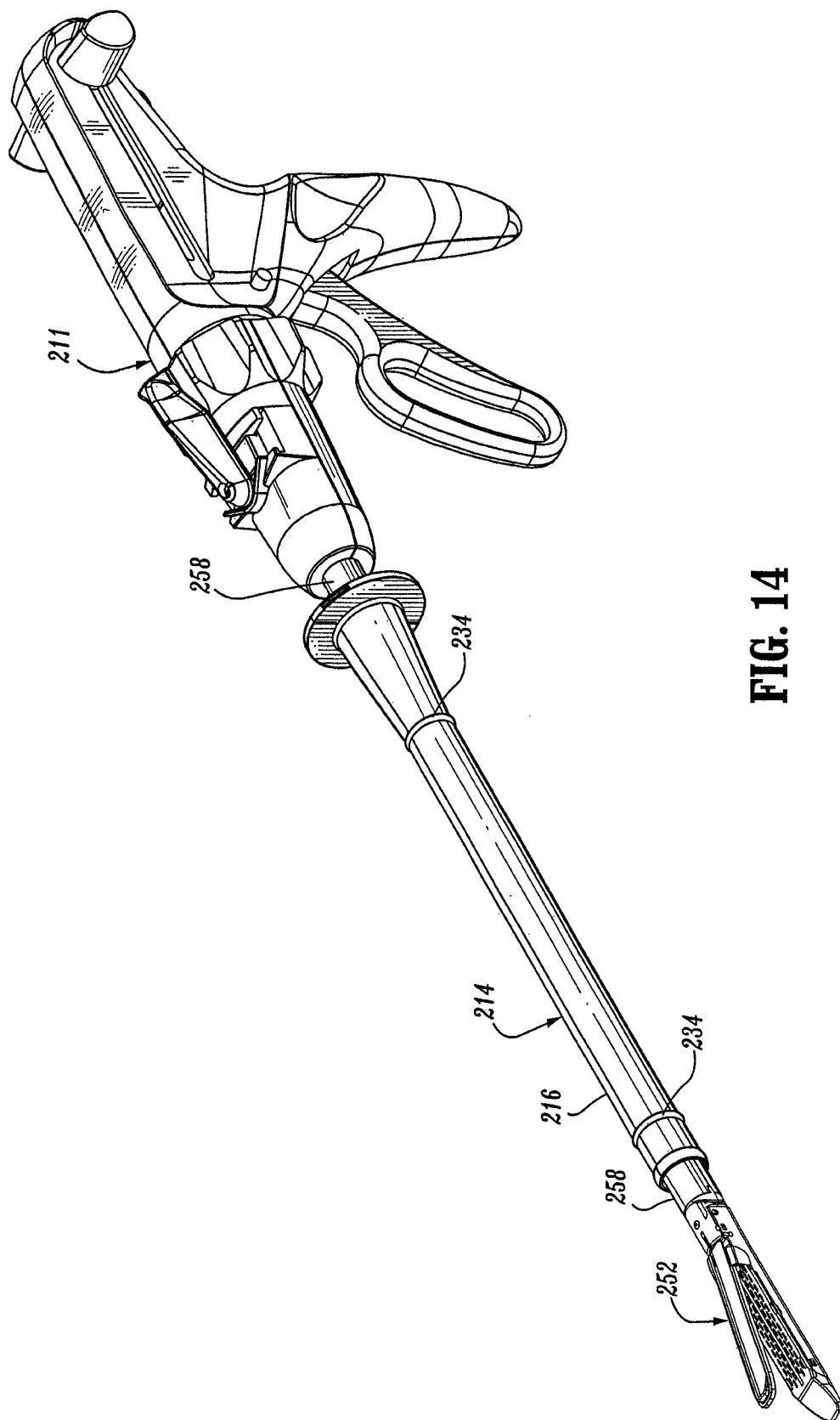


FIG. 14

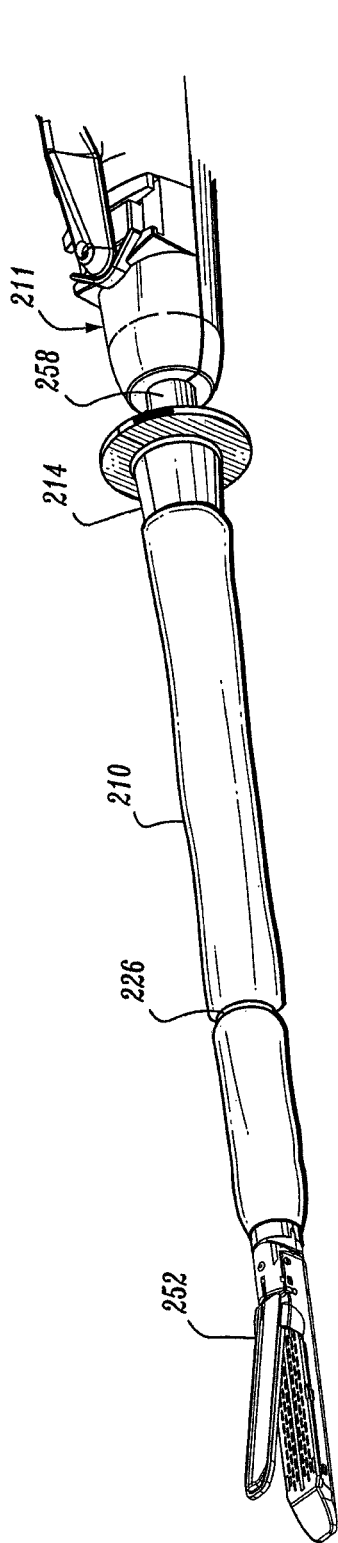


FIG. 15

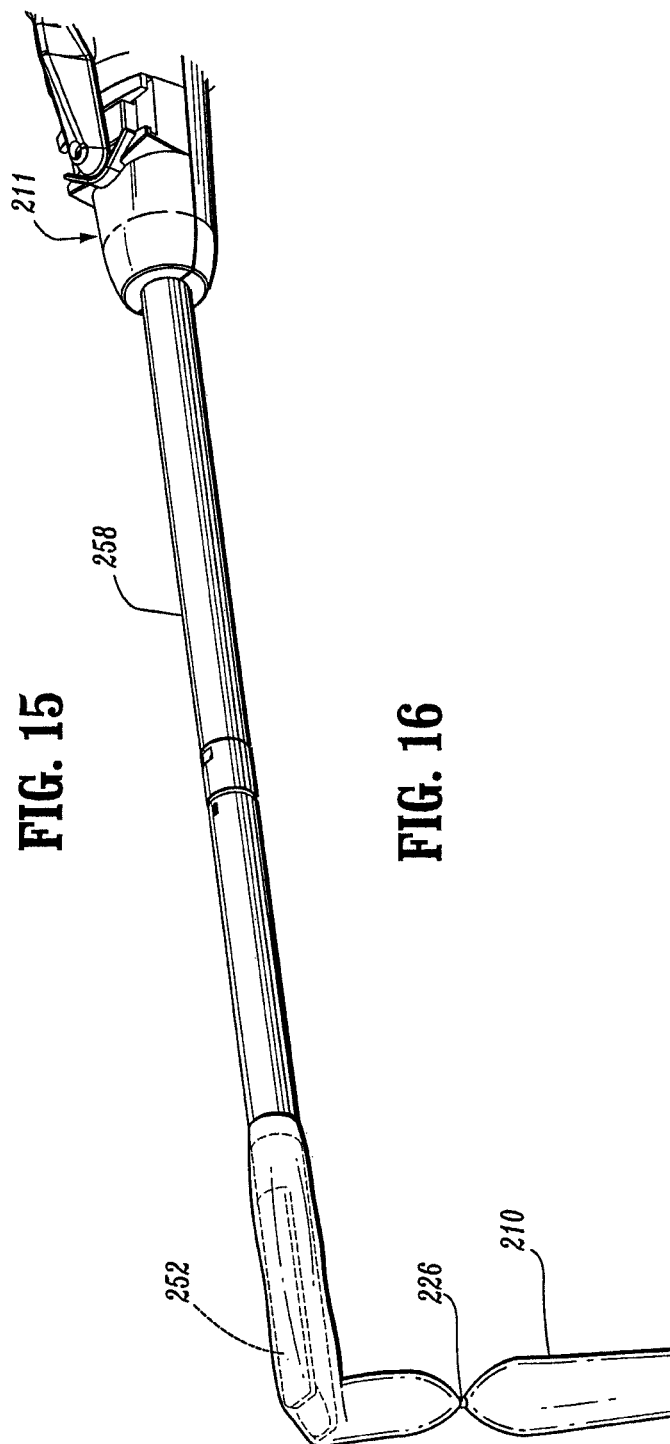


FIG. 16

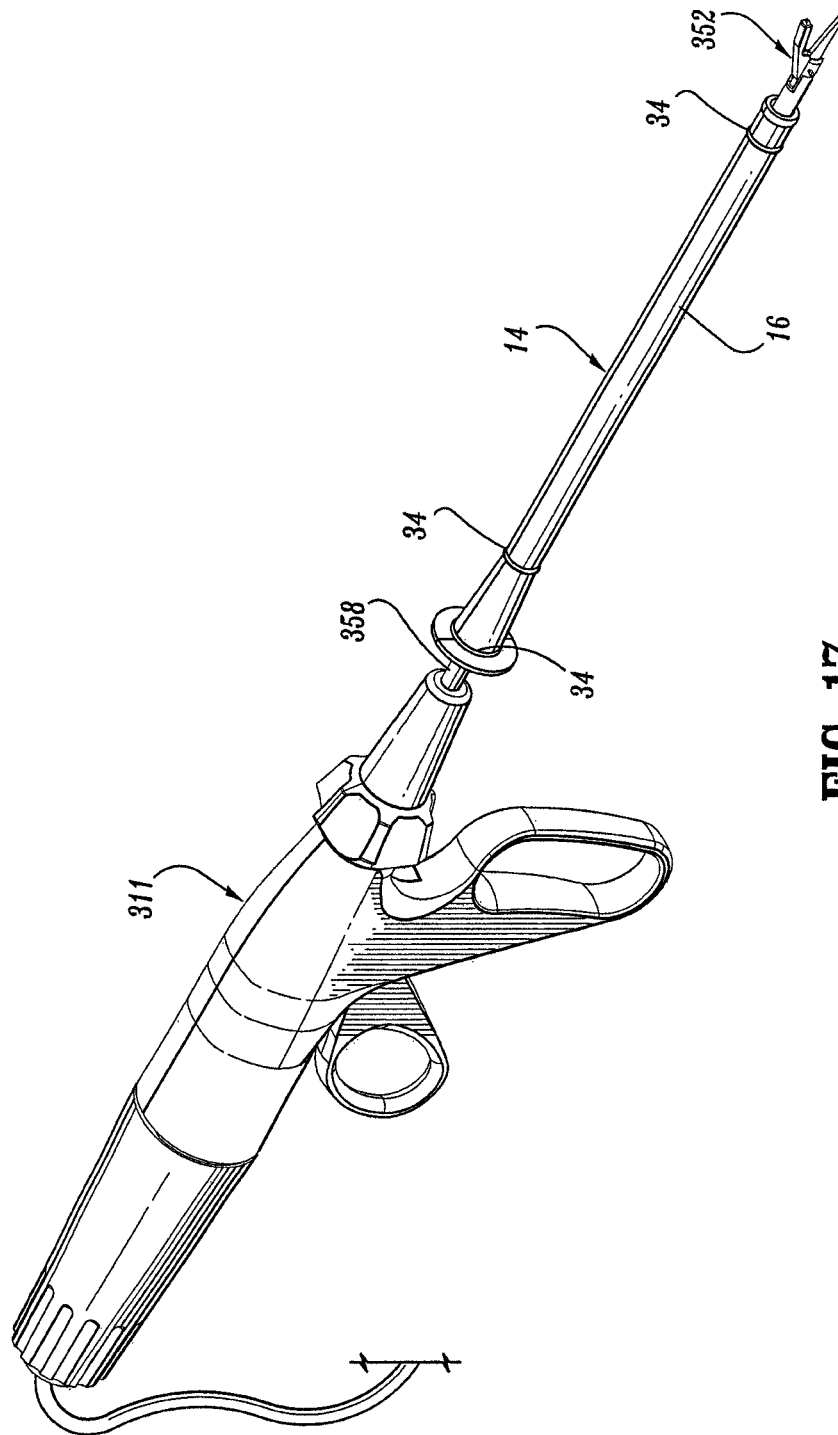
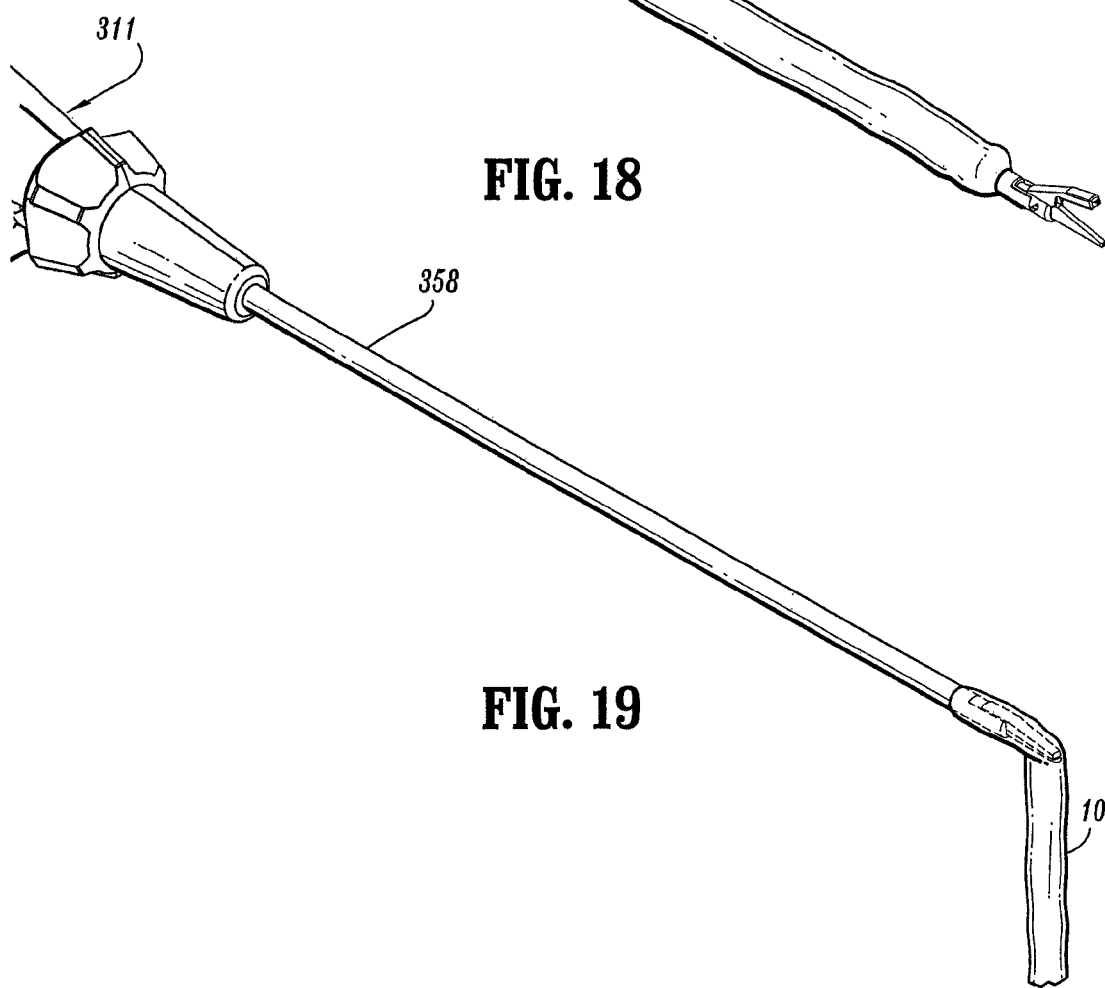
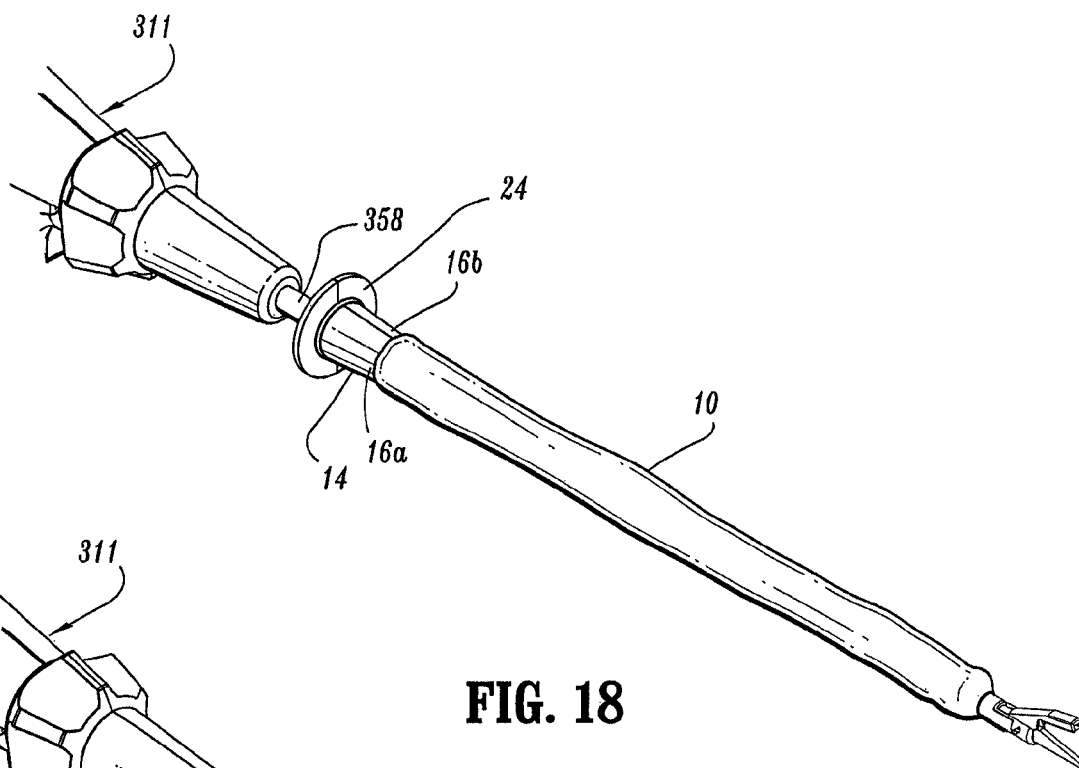


FIG. 17



TOOL MEMBER COVER AND COVER DEPLOYMENT DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 10/522,914 filed Jan. 28, 2005, which is a 371 of application No. PCT/US03/24201 filed Jul. 31, 2003, which claims the benefit of and priority to U.S. Provisional Application Ser. No. 60/400,328, filed Jul. 31, 2002, the entire contents of which are incorporated herein by reference.

BACKGROUND

1. Technical Field

This application relates to a cover and cover deployment device for the tool member or tool assembly of a surgical instrument, and more particularly, to a cover and cover deployment device for the tool member of a laparoscopic or endoscopic surgical instrument for manipulating, treating or excising tissue, especially diseased or cancerous tissue, from a body cavity.

2. Background of Related Art

A variety of different types of surgical instruments have been developed for manipulating, identifying, treating, repairing and/or excising tissue including organs or portions thereof located within body cavities such instruments sometimes being hereafter referred to as surgical instruments for treatment of body tissues. These instruments include graspers, fasteners, e.g., staplers, dissectors, biopsy devices, coagulators, etc. Typically, these instruments are dimensioned to be used in both open and laparoscopic or endoscopic procedures.

In endoscopic surgical procedures for treatment of body tissue, a surgical instrument is inserted through an incision or cannula to a position adjacent the tissue to be treated. The distal tool member of the instrument is then manipulated to treat, i.e., biopsy, excise, dissect, coagulate, reposition, etc., the tissue. Thereafter, the instrument with or without excised tissue is withdrawn from the surgical site through the incision to remove the instrument from the body cavity.

One problem associated with current surgical devices is that during removal of the tool member from the surgical site, the tool member or tool assembly (hereafter, for simplicity "tool member") of the surgical instrument for treating, for example, diseased, tissue comes into contact with the healthy tissue defining the incision and/or within the body cavity in which the surgical site is located. This may also be a problem in open surgical procedures. Where the tissue being treated is diseased tissue, e.g., cancerous, this problem becomes critical since contact between the cancerous tissue and the healthy tissue may result in seeding of cancerous cells resulting in metastases.

Accordingly, a need exists in the art for improved instrumentation for shielding healthy tissue from diseased tissue during removal of a surgical instrument from a surgical site.

SUMMARY

The present disclosure provides a tool member cover for use with a surgical instrument having a tool assembly and a body portion. The cover is preferably tubular and has open distal and proximal ends. A portion of the cover, preferably the distal end, is fastened to the surgical instrument adjacent to or on the tool assembly. Alternately, the cover may be removably attached to the surgical instrument. The cover is

movable from a first position in which the tool member is uncovered to a second position in which the cover at least partially encompasses the tool member.

Preferably, the cover is formed of an impermeable material. A deployment device is provided for moving the cover from the first position to the second position. In a first embodiment, the deployment device includes a sleeve formed of half-sections which are held together using expandable members, e.g., resilient O-rings. The O-rings allow the sleeve half-sections to move outwardly relative to each other to allow the sleeve to pass over a tool assembly having a larger diameter than a body portion of the surgical instrument. The sleeve is slidably positioned about the body of a surgical instrument between retracted and advanced positions to move the cover from the first position to the second position. The cover is positioned about the body portion of the surgical instrument and about the deployment device such that when the deployment device is moved from the retracted to the advanced position, the distal end of the sleeve engages the distal end of the cover to invert the cover over the tool assembly.

The cover may include a closure device such as a draw-string or elastic band to close the distal end of the cover to enclose the tool member within the cover. The cover may be used with a variety of different types of surgical instruments including staplers, fasteners, manipulators, biopsy devices, retractors, coagulators, dissectors etc.

BRIEF DESCRIPTION OF THE DRAWINGS

Various preferred embodiments of the presently disclosed tool member cover and cover deployment device are described herein with reference to the drawings, wherein:

FIG. 1 is a perspective view of one preferred embodiment of the presently disclosed tool member cover and cover deployment device, with parts separated, positioned about an unapproximated circular surgical stapler;

FIG. 2 is a side perspective view of the deployment device sleeve with parts separated of the deployment device shown in FIG. 1;

FIG. 3 is a side perspective view of the deployment device sleeve shown in FIG. 2;

FIG. 4 is a perspective cutaway view of the distal end of the deployment device sleeve shown in FIG. 3 fastened together with an O-ring;

FIG. 5 is a perspective view of the deployment device shown in FIG. 3 positioned about the body portion of an unapproximated circular surgical stapler with the sleeve halves in an expanded configuration;

FIG. 6 is a side perspective view of the deployment device of FIG. 5 in a contracted configuration, shown positioned about the body portion of an unapproximated circular surgical stapler;

FIG. 7 is a side perspective view of the tool member cover and cover deployment device of FIG. 1 positioned about the body portion of an unapproximated circular surgical stapler with the cover and deployment device in a retracted position and the deployment device in a contracted configuration;

FIG. 8 is a side perspective view of the tool member cover and cover deployment device of FIG. 7 positioned about the body portion of an approximated circular surgical stapler with the cover and deployment device in a retracted position and the deployment device in a contracted configuration;

FIG. 9 is a side perspective view of the tool member cover and cover deployment device of FIG. 7 positioned about the body portion and tool assembly of a circular surgical stapler

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with the cover and deployment device in a partially advanced position and the deployment device in an expanded configuration;

FIG. 10 is a side perspective cutaway view of the tool member cover deployed about the tool member of an approximated circular surgical stapler;

FIG. 11 is a side perspective view of another preferred embodiment of the presently disclosed cover deployment device;

FIG. 12 is a side perspective view with portions broken away of the cover deployment device shown in FIG. 11 supported on a body portion of an unapproximated circular surgical stapler;

FIG. 13 is a side perspective view with portions broken away of the tool member cover and cover deployment device shown in FIG. 12 supported on a body portion of an unapproximated circular surgical stapler with the deployment device and cover in retracted positions;

FIG. 14 is a side perspective view of the cover deployment device shown in FIG. 1 positioned about the body portion of endoscopic gastrointestinal anastomosis linear stapler;

FIG. 15 is a side perspective view with portions broken away of another preferred embodiment of the tool member cover and the cover deployment device shown in FIG. 1 positioned about the body portion of the endoscopic gastrointestinal anastomosis linear stapler of FIG. 15 and with the cover and deployment device in retracted positions;

FIG. 16 is a side perspective view of the tool member cover in a deployed configuration positioned about the tool member of the endoscopic gastrointestinal anastomosis linear stapler of FIG. 15;

FIG. 17 is a side perspective view of the cover deployment device shown in FIG. 1 positioned about the body portion of an ultrasonic dissection device;

FIG. 18 is a side perspective view of the tool member cover and cover deployment device shown in FIG. 1 positioned about the body portion of the ultrasonic dissection device of FIG. 17 with the tool member cover and deployment device in retracted positions; and

FIG. 19 is a side perspective view of the tool member cover in a deployed configuration about the tool member of the ultrasonic dissection device of FIG. 18.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Preferred embodiments of the presently disclosed tool member cover and cover deployment device will now be described in detail with reference to the drawings in which like reference numerals designate identical or corresponding elements in each of the several views.

FIG. 1 illustrates one preferred embodiment of the presently disclosed tool member cover and cover deployment device. Briefly, tool member cover 10 includes a collapsible flexible material which is preferably liquid impermeable and formed from one or more layers of a suitable plastic, preferably, polyethylene. Alternately, other liquid impermeable materials, woven or non-woven, natural or synthetic, and suitable for surgical use may be used to construct the cover, e.g., rubber, elastomers, polytetrafluoroethylene, etc. Cover 10 is preferably tubular and defines a lumen 12 dimensioned or configured to receive the body portion 58 of a surgical instrument 11. Preferably, but not necessarily, the distal end 10a of cover 10 has a smaller diameter than the proximal end of cover 10. A portion of cover 10 is preferably fastened to the surgical instrument. The distal end 10a of cover 10 is dimensioned or configured to be fastened directly onto or adjacent

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to a tool member 52 or a shaft that adjoins a tool member or a handle of a surgical instrument 11. Alternately, cover 10 may have a constant diameter along its entire length or the proximal end of cover 10 may have a smaller diameter than the distal end of cover 10. Cover 10 is preferably fastened to the surgical instrument in a liquid impermeable manner. Cover 10 may also be removably attached to the surgical instrument.

Referring also to FIGS. 2-4, cover deployment device 14 (FIG. 5) includes a sleeve 16 formed of sleeve half-sections 16a and 16b. Sleeve half-section 16a includes a pair of extensions 18 which are dimensioned to be slidably received within slots 20 formed in sleeve 16b. Each sleeve half-section 16a and 16b includes a proximal end 22 having a flange or semi-annular ring 24, a centrally positioned semi-annular recess 25, a distally positioned semi-annular recess 26 and a proximally positioned semi-annular recess 27. The distal end 28 of each sleeve 16a and 16b includes a semi-annular blunt protrusion 30. The function of protrusion 30 will be discussed in detail hereinbelow.

Referring to FIGS. 2-4, sleeve half-sections 16a and 16b are positioned in abutting relationship, with extensions 18 slidably positioned in slots 20 to define a lumen 32 dimensioned to slidably receive or be positioned about a portion of the body of surgical instrument 11. An expandable member, preferably resilient O-ring 34 (FIG. 1), is positioned in each of annular recesses 25, 26 and 27. O-rings 34 are stretchable from a contracted position to an expanded position to allow sleeve half-sections 16a and 16b to move in relation to each other between contracted and expanded positions (FIGS. 3, 4 and 9, respectively). In the contracted position, sleeves 16a and 16b are preferably held in abutting relation with extensions 18 fully inserted within slots 20.

Referring to FIG. 5, sleeve half-sections 16a and 16b are configured to be easily assembled about the elongated body portion 58 of surgical instrument 11 such that the distal end 28 of sleeve 16 is positioned adjacent a tool assembly 52 of surgical instrument 11. Although surgical instrument 11 is illustrated as a circular stapler, it is envisioned that the surgical instrument may be any of a wide variety of instruments for performing a wide variety of functions including cutting, fastening, manipulating, treating, dissecting, coagulating and biopsying tissue. Such instruments include retractors, biopsy devices, dissectors, coagulators, fasteners, staplers, including linear staplers, circular stapler, semi-circular staplers, arc shaped staplers, etc.

Referring also to FIGS. 6 and 7, in the illustrated embodiment, circular stapler 11 includes an unapproximated tool assembly 52 having an anvil 54, a shell assembly 56 and an elongated body 58. One known circular stapler is disclosed in PCT application Serial No. PCT/US02/10792, which is incorporated herein in its entirety by reference. Sleeve 16 is expandably and slidably positioned about elongated body 58 such that protrusion 30 is positioned adjacent to shell assembly 56. The distal end 10a of cover 10 is preferably secured adjacent to or on the proximal portion of tool assembly 52 at a fastening point or securement 60 (FIG. 7) using a known fastening technique, e.g., adhesion, fusion, crimping, pins, clips etc. and is positioned about sleeve 16 and body portion 58 of surgical instrument 11. Alternately, cover 10 may be releaseably secured to the instrument using known techniques including springs, tabs, hooks, etc. Annular protrusion 30, which is formed at the distal end 28 of sleeve 16, is positioned proximally of fastening point or securement 60.

It is understood that cover 10 can be secured at any suitable location along shaft 58, although on some instruments secur-

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ing it close to or even on the tool member itself will save cover material and will render the cover easier to manipulate with or without tissue therein.

Referring to FIGS. 8-10, in the illustrated embodiment, the distal end 10a of cover 10 is fastened to the proximal portion of shell assembly 56 of tool assembly 52. In use, surgical instrument 11 is positioned such that tool assembly 52 is located adjacent the surgical site. During an endoscopic surgical procedure, this would include inserting the tool assembly 52 and a portion of body portion 58 through an incision with cover 10 and cover deployment device 14 supported about elongated body portion 58 of surgical instrument 11. Thereafter, the surgical instrument is manipulated to perform its associated or designed function. With respect to a circular stapler, body tissue (not shown) is positioned between an unapproximated anvil 54 and shell assembly 56 using, for example, a purse string suture (not shown). Next, the anvil 54 and shell assembly 56 are approximated and surgical instrument 11 is fired in a known manner to dissect tissue and apply a circular array of staples to the dissected and remaining tissue. After surgical instrument 11 has performed its associated function but prior to removal of tool assembly 52 from the surgical site, annular ring 24 of sleeve 16 is pushed forward manually, mechanically, remotely, or robotically in the direction indicated by arrows "A" in FIG. 9 to advance sleeve 16 about body 58 of surgical instrument 11. As sleeve 16 is advanced, annular protrusion 30 engages distal end 10a to invert cover 10 about securement 60 and gradually about cover 10 proximally of secured or attached tool assembly 52. Annular protrusion 30 includes a smooth or blunt surface to prevent tearing of cover 10 during advancement. Because tool assembly 52 has a diameter larger than body 58, at least the distal end portions of sleeve half-sections 16a and 16b expand outwardly in relation to each other by stretching O-rings 34 as distal end 28 of sleeve 16 rides over tool assembly 58. It is noted that in surgical instruments having a tool assembly having a diameter equal to or less than the diameter of the body of the surgical instrument, stretchable o-rings would not be required. When sleeve 16 has been advanced to fully deploy cover 10 about and preferably beyond tool assembly 52 (FIG. 10), the cover deployment device can be withdrawn to its retracted position about body 58 of surgical instrument 11. Surgical instrument 11 including tool assembly 52 and incised tissue therein or thereabout (not shown) and enclosed by cover 10 can now be withdrawn from the surgical site without exposing the healthy tissue defining the incision and within the body cavity (not shown) to diseased tissue on or in the tool assembly.

FIGS. 11-13 illustrate another preferred embodiment of the presently disclosed cover deployment device shown generally as 116. It is noted that the deployment devices disclosed herein are only exemplary embodiments. Any suitable deployment device capable of positioning a cover over a tool assembly of a surgical instrument after it has been used in a surgical procedure is within the scope of this disclosure. Cover deployment device 116 includes a semi-rigid body portion 122 having a proximal semi-annular guide portion 124 and a distal semi-annular engagement member 126. Semi-annular engagement member 126 is preferably formed of a sufficiently, diametrically and radially resilient material and is configured and dimensioned to engage the proximal end of a tool assembly 152 of a surgical instrument 111. Proximal guide portion 124 is configured to partially encompass body portion 158 of surgical instrument 111 and to be pushed by a surgeon to operate deployment device 116. Body portion 122 of deployment device 116 interconnects guide

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portion 124 and engagement member 126 and is sufficiently rigid to transfer the imparted pushing force to the engagement member 126.

The distal end 110a of cover 110 is secured to surgical instrument 111 adjacent to or on a proximal portion of tool assembly 152 in the manner described above with respect to cover 10, such that cover 110 is positioned about deployment device 116 and body 158 of surgical instrument 111. Engagement member 126 is positioned slightly proximally of a fastening point 160 of cover 110 and to tool assembly 152. In use, deployment device 116 is advanced about body 158 of surgical instrument 111 by pushing on guide portion 124 to advance engagement member 126 into the distal end of cover 110 to invert cover 110 about tool assembly 152 in a manner similar to that disclosed above. Because engagement member 126 is flexible, it is able to slide over the increasing diameter of tool assembly 152. After cover 110 is fully deployed (not shown), deployment device 116 can be retracted and surgical instrument 111 can be removed from a surgical site.

It is to be noted that the distal end 110a of cover 110 can be secured to tool assembly 152 or a similar or like operating end to end anastomosis device that does not require holes such as "H" (FIG. 12) to vent directly to the atmosphere.

FIGS. 14-16 illustrate another preferred embodiment of tool assembly cover 210 and cover deployment device 214 including sleeve 216 positioned about a body portion 258 of an endoscopic gastrointestinal anastomosis linear stapler 211. Such a stapler is described in detail in U.S. Pat. No. 6,241,139 which issued on Jun. 5, 2001 and is incorporated herein in its entirety by reference. The cover deployment device 216 is substantially identical in structure and use as the deployment device described in FIGS. 1-10 and will not be described in further detail herein. Cover 210 is substantially identical to cover 10 described above but further includes an elastic band 226 formed about, within or integrally with a central portion of cover 210. Cover 210 is deployed in a manner substantially identical to that disclosed above. However, as shown in FIG. 16, when elastic band 226 is forced over the distal end of tool assembly 252 of surgical instrument 211, elastic band 226 contracts to close cover 210 about tool assembly 252. The enclosed bag prevents tissue and/or body fluids from escaping cover 210 and infecting healthy tissue in the body cavity or in the incision. It is noted that one or more elastic band(s) 226 may be employed with or incorporated into any of the covers disclosed herein.

FIG. 17-19 illustrate tool assembly cover 10 and cover deployment device 14 shown in FIGS. 1-6 positioned about body 358 of an ultrasonic dissector instrument 311. Such an instrument is disclosed in U.S. Pat. No. 6,024,750 which issued on Feb. 14, 2000 and is incorporated herein in its entirety by reference. As illustrated, cover 10 is preferably fastened to the distal end of elongated body 358 of instrument 311 proximally of a tool assembly 352 of instrument 311 such that when cover 10 is deployed, in the manner discussed above with respect to FIGS. 1-6, tool assembly 352 and/or contaminated or treated tissue is encompassed by cover 10 (FIG. 19).

While the invention has been particularly shown and described with reference to the preferred embodiments, it will be understood by those skilled in the art that various modifications and changes in form and detail may be made therein without departing from the scope and spirit of the invention. For example, a closure device other than an elastic band may be provided to close the cover about the tool assembly. For example, a drawstring "D" (FIG. 10) may be provided which can be grasped at the surgical site using graspers to close the cover 10 or the drawstring may be fed through the surgical

instrument and be accessible from the proximal portion of the surgical instrument. Further, the cover need not be inverted about the tool assembly but rather may be slid directly over the tool assembly. Also, the cover may be configured to not only encompass the tool assembly but may also be configured to encompass a distal portion or the entire body portion of the surgical instrument. Accordingly, modifications such as those suggested above, but not limited thereto, are to be considered within the scope of the invention.

What is claimed is:

1. A surgical instrument for insertion into a body lumen comprising:

an elongated body portion having an outer surface;

a tool assembly supported on a distal end of the elongated body portion;

a cover fitted about the elongated body portion, the cover movable from a first proximal position to a second position to cover a distal end of the tool assembly, the cover having a distal end secured to the elongated body portion adjacent the tool assembly; and

a cover deployment member separable from the cover, the cover deployment member being positioned about the elongated body portion between the elongated body portion and the cover and being slidable in a distal direction along the body portion to move the cover to the second position.

2. A surgical instrument according to claim 1, wherein the cover deployment member is releasably engaged with the cover.

3. A surgical instrument according to claim 2, wherein the cover deployment member includes a sleeve slidably positioned about the body portion between a retracted position and an advanced position to move the cover from the first proximal position to the second position.

4. A surgical instrument according to claim 3, wherein the sleeve includes first and second half-sections, the first and second half-sections being urged into abutment with one another by at least one expandable member, the expandable member being expandable to permit the first and second half-sections to move outwardly with respect to each other.

5. A surgical instrument according to claim 4, wherein the expandable member is a resilient O-ring.

6. A surgical instrument according to claim 4, wherein the sleeve includes a proximally located annular ring dimensioned to facilitate movement of the sleeve between the retracted and advanced positions.

7. A surgical instrument according to claim 4, wherein the first sleeve half-section includes at least one projection and the second sleeve half-section includes at least one slot, the at least one projection being slidable into the at least one slot to maintain alignment between the first and second half-sections when the first and second half-sections move outwardly with respect to each other.

8. A surgical instrument according to claim 1, wherein the cover is fitted about the elongated body portion such that movement of the cover deployment member from the retracted position to the advanced position inverts the cover over the tool assembly.

9. A surgical instrument according to claim 1, wherein the cover deployment member includes a distal engagement member, a proximal guide portion and a central body portion interconnecting the engagement member and the guide portion, the cover deployment device being slidably supported on the elongated body portion to enable the cover deployment member to be moved to move the cover to the second position.

10. A surgical instrument according to claim 1, further including a closure device configured to enclose a proximal end of the cover after the cover is in the second position.

11. A surgical instrument according to claim 10, wherein the closure device includes an elastic band supported by the cover.

12. A surgical instrument according to claim 10, wherein the closure device includes a drawstring.

13. A surgical instrument according to claim 1, wherein the surgical instrument is a circular stapler.

14. A surgical instrument according to claim 1, wherein the surgical instrument is an ultrasonic dissector.

15. A surgical instrument according to claim 1, wherein the surgical instrument is a linear stapler.

16. A surgical instrument according to claim 1, wherein the tool assembly includes a stationary shell having a plurality of staples.

17. A surgical instrument for insertion into a body lumen comprising:

an elongated body portion;

a tool assembly supported on a distal end of the elongated body portion;

a cover having open proximal and distal ends and defining a lumen between the proximal and distal ends, the distal end of the cover attached to the surgical instrument adjacent a proximal end of the tool assembly, the cover being movable from a proximal position in which a portion of the elongated body portion is disposed within the lumen of the cover to a distal position in which the tool assembly of the surgical instrument is disposed within the lumen of the cover; and

a cover deployment member having an annular engagement portion extending at least partially about the elongated body portion, the cover deployment member being slidable about the elongated body portion to engage and move the cover from the proximal position to the distal position.

18. A surgical instrument according to claim 17, wherein the cover deployment member is separable from the cover.

19. A surgical instrument for insertion into a body lumen comprising:

an elongated body portion;

a tool assembly supported on a distal end of the elongated body portion;

a cover having open proximal and distal ends and defining a lumen between the proximal and distal ends, the distal end of the cover attached the surgical instrument adjacent a proximal end of the tool assembly, the cover being movable from a proximal position in which a portion of the elongated body portion is disposed within the lumen of the cover to a distal position in which the tool assembly of the surgical instrument is disposed within the lumen of the cover; and a cover deployment member having an annular engagement portion extending at least partially about the elongated body portion, the cover deployment member being slidable about the elongated body portion to engage and move the cover from the proximal position to the distal position, the cover deployment member including a first half-section and a second half-section coupled together by at least one expandable member such that the cover deployment member is movable between a contracted configuration and an expanded configuration, the annular engagement portion having a diameter less than the diameter of the tool assembly in the contracted configuration and a diameter greater than the diameter of the tool assembly in the expanded configuration, wherein the first and sec-

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ond half-sections of the annular engagement portion are configured to expand outwardly to the expanded configuration as the annular engagement portion rides over the tool assembly.

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